May 6, 2011

Medical Device Labeling for Health Care Practitioners Focus Group Study

FINAL REPORT

Presented to

Food and Drug Administration

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RTI Project Number 0212305.009.001

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Introduction and Methods

Introduction

This report summarizes key findings from a focus group study conducted by RTI International as part of the "Food and Drug Administration (FDA) Medical Device Labeling" project. Specific research objectives for the focus group study were the following:

- To explore current awareness and use of medical device labeling by health care practitioners.
- To assess which aspects of device labeling are most important and most likely to be read by health care practitioners.
- To explore possible changes to labeling content.
- To explore practitioners' satisfaction with current device labeling formatting.

First, we describe the design and methods of the focus groups. Second, we specify modifications made to the interview guide on site and limitations of the research. Third, we describe participant characteristics. Fourth, we report findings from the focus groups. Finally, we provide some recommendations for changes to practitioner device labeling as a result of the focus groups.

Study Design

In-person focus groups were conducted to examine factors relating to device labeling awareness, use, content, and format. Office of Management and Budget (OMB) clearance was secured for the research by FDA as was RTI Institutional Review Board (IRB) clearance.

We conducted six focus groups with a sample of healthcare practitioners in Philadelphia, New York City, and Boston in March 2011. Practitioners were eligible to participate if they were physicians, physician assistants, nurse practitioners, respiratory therapists, technicians, nurse wound care specialists, or nurses (LPN or RN), in one of three specialties: respiratory therapy, infusion therapy, or wound care. In addition, the participants must have been in practice between 3 and 25 years. In recruitment, we sought a mix of gender and length of time in practice.

Methods

Participants from each city were recruited by a professional focus group recruitment firm; Schlesinger Associates, using a questionnaire used to screen participants for eligibility. This screening instrument was developed collaboratively by RTI and FDA (see Appendix A for the recruitment screeners). Before beginning the interview, participants were asked to read and sign an informed consent form (see Appendix B). Participants returned one copy of the form to the facility staff and kept one copy for themselves.

All focus groups lasted from 60 to 90 minutes and were conducted at professional focus group facilities in each of the three cities. An experienced RTI moderator led the discussions using a semistructured discussion guide developed collaboratively by RTI and FDA (see Appendix C for the

focus group discussion guides). At the conclusion of the focus group session, participants filled out an optional demographic questionnaire (see Appendix D). A member of RTI's research team observed the focus groups and took notes from behind a one-way mirror in Philadelphia and watched videorecordings of the focus groups in New York City and Boston. Staff from FDA observed in Philadelphia. All focus groups were audio and, in New York City and Boston, video recorded and transcripts were made of the audio files. Participants were provided an incentive at the conclusion of the discussion to thank them for their participation and compensate them for travel costs. The section "Participant Characteristics" shows participant demographic information.

Instrument Modifications of Guides

We made modifications to the focus group guides during the first phase (in Philadelphia) to further probe participants on the concept of a central repository of device labeling and on their awareness of changes to labeling:

- For Q21, added "Probe: would it be helpful to have all device labels available on one website (similar to DailyMed)? What type of labeling should be on that site (full labeling or highlights only)?"
- For Q22, added "Probe: is it the same for both new and old devices?"

Limitations of Research

As with all qualitative methods of research, it should be noted that results are not generalizable and therefore cannot be extended to wider populations. Qualitative research is valuable in that it is used to gain insight into people's attitudes, behaviors, value systems, concerns, and motivations in a way that provides a rich amount and quality of data.

Participant Characteristics

A total of 77 health care practitioners participated in nine focus groups. Three focus groups were conducted in each of the following cities: Philadelphia (n=24, 31%), New York City (n=26, 34%), and Boston (n=27, 35%). The sample consisted of health care practitioners specializing in respiratory therapy (n=27, 35%), infusion therapy (n=26, 34%), and wound care (n=24, 31%). Focus groups were segmented by job roles including prescribers (e.g., physicians, physician assistants, and nurse practitioners) (n=26, 34%), nurses (n=26, 34%), nurse wound care specialists (n=16, 21%), and respiratory therapists (n=9, 12%). Table 1 provides the focus group segmentation including the number of participants by segment.

Table 1. Focus Group Segmentation including Number of Participants per Group

	Respiratory therapy	Infusion therapy	Wound care	Total number of focus groups
Prescribers[a]	1 (n=9)	1 (n=9)	1 (n=8)	3 (n=26)
Nurses	1 (n=9)	2 (n=9, n=8)		3 (n=26)
Respiratory therapists	1 (n=9)			1 (n=9)
Nurse wound care specialists			2 (n=7, n=9)	2 (n=16)
Total number of focus groups	3 (n=27)	3 (n=26)	3 (n=24)	9 (n=77)

[a] Physicians, physician assistants, and nurse practitioners.

Table 2 provides the characteristics of the 77 focus group participants. In general, characteristics were similar regardless of location and specialty. Forty-one (53%) of the participants worked in hospitals, 19 (25%) worked in outpatient clinics, eight (10%) worked in office-based private solo or group practices, three (4%) worked in rehabilitation settings, one person (1%) worked in a home health setting, one person (1%) worked in a nursing home, and one person (1%) worked in both a hospital and private practice. Most participants (77%) primarily worked in urban whereas 21% primarily worked in a suburban setting. On average 40% of the participants' patient populations were Caucasian/White, 30% were African American/Black, 7% were Asian or Pacific Islander, and 1% were from other racial/ethnic groups. The primary patient age range of 55% of the focus group participants was 36 to 64 years, 20% of the participants primarily served patients 65 years and older, and 5% primarily served patients 0 to 18 years of age.[1] Most participants' primary cost reimbursement method at their primary practice location was Medicare/Medicaid (52%), followed by private insurance (30%), and other unspecified cost reimbursement methods (3%).[2]

[1] It should be noted that 11 participants (14%) did not indicate the age of their primary patient population.
[2] Sixteen percent of participants did not indicate the cost reimbursement method primarily used by their patients.

Table 2. Focus Group Participant Characteristics

City		**n**	**%**
	New York City	26	33.8
	Boston	27	35.1
	Philadelphia	24	31.2
	Total	77	100.0
Specialty		**n**	**%**
	Respiratory therapy	27	35.1
	Infusion therapy	26	33.8
	Wound care	24	31.2
	Total	77	100.0
Segment		**n**	**%**
	Practitioner	26	33.8
	Nurse	26	33.8
	Nurse wound care specialist	16	20.8
	Respiratory therapist	9	11.7
	Total	77	100.0
Workplace		**n**	**%**
	Hospital	41	53.3
	Home health	3	3.9
	Inpatient wound care clinic	1	1.3
	Nursing home	1	1.3
	Office based or private solo/group practice	8	10.3
	Outpatient clinic	19	24.7
	Private practice/hospital	1	1.3
	Rehabilitation	3	3.9
	Total	77	100.0
1. What is the type of setting of your primary practice location?		**n**	**%**
	Urban	59	76.6
	Suburban	16	20.8
	No answer	2	2.6
	Total	77	100.0
2. What is the approximate racial/ethnic makeup of your patient population?		**Mean %[a]**	
	African American/Black	30.4	
	Hispanic/Latino	20.3	
	Caucasian/White	41	
	Asian or Pacific Islander	7.2	
	Other	1	
3. In general, what is the primary age of your patient population?		**n**	**%**
	0-18	4	5.2
	19-35	0	0
	36-64	42	54.5
	65+	20	26
	No answer	11	14.3
	Total	77	100.0

Table 2. Focus Group Participant Characteristics (continued)

		n	%
4. In general, what is the primary cost reimbursement method at your primary practice location?		**n**	**%**
	Private insurance	23	29.9
	Medicare/Medicaid	40	51.9
	Other	2	2.6
	No answer	12	15.6
	Total	77	100.0
5. How many years have you been in practice (post-residency or post-licensure)?	**Average Years[b]**		
	17		
6. Do you have a role in training others to use medical devices?		**n**	**%**
	No	11	14.3
	Yes	66	85.7
	Total	77	100.0
7. What is your age?	**Average Age[c]**		
	45		
8. What is your race/ethnicity?		**n**	**%**
	African American/Black	8	10.4
	Hispanic/Latino	5	6.5
	Caucasian/White	51	66.2
	Asian or Pacific Islander	7	9.1
	Other	2	2.6
	No Answer	4	5.2
	Total	77	100.0
9. What is your gender?		**n**	**%**
	Female	54	70.1
	Male	20	26
	No answer	3	3.9
	Total	77	100.0

[a.] Twelve responses were missing and thus not included in the percent mean calculations. Data was recoded to missing if respondents indicated percentages for racial groups that did not sum to 100 percent.
[b.] Five participants did not indicate their number of years in practice.
[c.] Nine participants did not indicate their age.

On average, the participants reported being in practice (post-residency or post-licensure) for 17 years. The majority of participants (86%) indicated that they have a role in training others to use medical devices, whereas 14% indicated that they do not have a role in training others to use medical devices. Participants' mean age was 45 years; 70% were female and 26% were male.[3] Sixty-six percent of the participants were Caucasian/White, 10% were African American/Black, 9% were Asian or Pacific Islander, 7% were Hispanic/Latino, and 3% were from other racial/ethnic groups.[4]

[3] Three participants (4%) did not indicate their gender.
[4] Five percent of participants did not indicate their race.

Participant Characteristics by Segment

Although they had a few similar characteristics, the focus group participants' demographics varied most with regard to their job role or segment as shown in Appendix E. The nurse, nurse wound care specialists, and respiratory therapists primarily worked in urban settings (e.g., 73%, 69%, and 100% respectively) whereas the prescribers primarily worked in suburban settings (77%). Although the majority of participants in all segments indicated that they have a role in training others to use medical devices, more nurse wound care specialists (94%) indicated that they train others to use medical devices compared to other segments, followed next by respiratory therapists (89%), prescribers (85%), and nurses (81%). The nurse and respiratory therapist focus groups were more ethnically diverse than the prescriber and nurse wound care specialist focus groups. For example, the composition of Caucasian/White participants was 81% for both the prescriber and nurse wound care specialist focus groups, 56% for the respiratory therapist groups, and 44% for the nurse groups. The majority of the nurse and nurse wound care specialist participants were female, 81% and 94% respectively, whereas the prescriber and respiratory therapist focus groups had more balanced gender ratios (e.g., 50% female and 56% female respectively).

Participant Characteristics by Specialty

In general, the focus group participants shared similar demographic characteristics across the three specialties as shown in Appendix F. However, below we highlight some of the key differences between the specialties. Whereas the majority of participants in respiratory therapy (74%) worked primarily in a hospital, half of participants specializing in wound care (50%) and 35% of the participants specializing in infusion therapy worked in a hospital. At the same time, whereas half of infusion therapy participants (50%) primarily worked in an outpatient setting, only 25% of those in the wound care specialty and none of those in the respiratory specialty did the same. Although the majority of participants in all specialty groups indicated that they have a role in training others to use medical devices, a larger proportion of individuals specializing in respiratory therapy (96%) had a role in training others to use medical devices, followed by the infusion therapy participants (85%) and respiratory therapy participants (78%). The infusion therapy focus groups were composed of more African American/Black, Hispanic/Latino, and Asian or Pacific Islander participants and fewer Caucasian/White participants than the focus groups for the other two specialties. For example, the infusion therapy groups were composed of 15% African American/Black participants, whereas the respiratory therapy groups and wound care groups consisted of 7% and 8% African American/Black participants, respectively. The infusion therapy focus groups were made up of 39% Caucasian/White participants, whereas the respiratory therapy groups consisted of 74% Caucasian/White participants and the wound care groups consisted of 88% Caucasian/White participants.

Findings

Key Findings

Sections

- Irrespective of specialty, practitioner type, and geographic location, troubleshooting, instructions for use, warnings, precautions, contraindications, manufacturer's contact information (e.g., phone number for 24-hours technical support) along with the device name, serial number, and expiration date were identified as the most important sections in medical device labeling.
- Participants appreciate having the manufacturer's contact information on the labeling if they have questions about the device or the contents of the labeling.
- Health professional training, patient counseling, indications and usage, and cleaning and maintenance were identified as sections of medium importance by participants in all groups.
- All groups reported that clinical studies and references were least important sections of medical device labeling.

Format

- Participants noted the need to revise medical device labeling to make it concise and simple, and to use less technical language and fewer words, provide less information, include more pictures and diagrams to demonstrate instructions for use, device contents, and troubleshooting.
- Participants noted a need for color, larger font size, and more white space for ease of reading.
- Participants wanted a short and long version of the device label—one a detailed manual with all the information and another a short guide or a highlights document to include device name, troubleshooting, simple instructions for use (e.g., location of on/off button, how to plug into, and settings), warnings, contraindications, adverse effects, indications for use, diagrams showing instructions and device parts, cleaning instructions and manufacturer's name and contact information including Internet address where healthcare practitioners can access further details.
- Participants recommended that, when feasible, a medical device label, or a shorter version, should be attached to the device or in the form of a pocket card or should be available through technological modalities including the device's screen interface, iPhone application, DVD, CD, video, or online at manufacturer's website or FDA's website.
- A vast majority of participants indicated the need for hardcopy labeling supplemented by electronic versions.
- Diagrams and pictures, especially of instructions for use, troubleshooting, and device parts, were identified as an important area of improvement of medical device labeling by participants.
- Participants identified the need for better paper quality for hardcopy materials and lamination of hardcopy medical device labeling that may remain on the device.

Use of Labeling

- The nurse, nurse wound care specialist, and respiratory therapist participants more thoroughly read medical device labeling compared to prescriber participants. It appears that these groups read labels more often because they are responsible for disseminating labeling information and providing internal training to their staff or colleagues.
- Because participants are busy providing care to patients at work, they are more likely to refer to labeling information that is easy to read quickly and that they perceive to be useful.

- Participants are more likely to refer to labeling when they are unfamiliar with a device, to prevent a life-threatening circumstance for a patient, or when troubleshooting.

Access to Labeling

- All participants receive labeling information during an in-service training session, usually from a manufacturer's sales representative. They are usually satisfied with this process.
- Participants can more easily access medical device labeling online or directly on the medical device compared to a manual that can be difficult to find when needed.
- Participants generally favored having medical device labels housed on FDA.gov, but wanted to make sure the information was well organized on the site.

Changes to Labeling

- Prescribers do not expect to hear about changes to device labeling firsthand from the manufacturer; they expect to hear about changes through designated contacts in their settings.
- Nonprescribing practitioners (nurses, therapists, etc.) would like to hear about changes to device labeling in e-mail format from manufacturers.

General Discussion of Findings

As a warmup to the focus groups, participants were asked to discuss their workplace setting and name examples of the types of medical devices they use. Participants were then asked whether or not they read the labeling for the medical devices they described.

Respiratory Therapy Participants

Medical devices commonly used by the focus group participants specializing in respiratory therapy included nebulizers, pulse oximeters (e.g., CO_2 monitoring devices), and ventilators. The prescriber and nurse participants also said they use Continuous Positive Airway Pressure (CPAP) machines, inhalers, and CO_2 monitoring devices while the prescriber and respiratory therapist participants use Bi-level Positive Airway Pressure (BiPAP) machines. Other medical devices used by different segments of those specializing in respiratory therapy included the following:

- **Prescribers:** Laryngoscopes, endotracheal tubes, infusion pumps, nasal spray devices, and EpiPens.
- **Nurses:** Positive pressure devices, oxygen liquid concentrators, and anesthesia machines.
- **Respiratory Therapists:** Blood gas analyzers or blood gas machines.

Workplace settings of the focus group participants were described earlier in the "Participant Characteristics" section of this report. Because 74% of the respiratory therapy focus group participants worked in hospital settings, it was difficult to note differences in use of devices by setting. Regarding reading labels, participants differed in their responses:

- Three of nine respiratory prescribers said they read medical device labeling.

- Six of nine respiratory therapists said they read medical device labeling.

- All of the respiratory therapy nurses (nine of nine) said they read medical device labeling. However, four nurses admitted that they only *sometimes* read this labeling. One nurse in particular noted, “If I know what the equipment is I tend not to probably read the label as much as I should." (Nurse, Respiratory Therapy, Boston)

Infusion Therapy Participants

Both the prescriber and nurse participants specializing in infusion therapy use dialysis machines and intravenous therapy (IV) pumps. Other medical devices used by focus group participants specializing in infusion therapy included the following:

- **Prescribers:** Temporary catheters, hemodialysis machines, devices for administering intravenous immunoglobulin (IVIG), insulin pumps.

- **Nurses:** Electrocardiography (EKG) machines, pump supports, infusion needles, peripherally inserted central catheters (PICC), and special dressings.

In general, there was not much difference in use of devices among various settings, although participants mentioned that there are certain dialysis machines and infusion pumps specific to home use. The prescribers and nurses responded differently to the question of whether they read medical device labeling. No prescriber participants specializing in infusion therapy routinely read device labeling. However, situations where prescribers might read labeling included when they are trying to determine the needle gauge size for a patient or if they are unfamiliar with a device.

> *When we’re making a change or maybe looking at a new device we do the reading, but once you’re familiar with it you probably don’t look too much at the instructions, but encourage the patients to do so. (Prescriber, Infusion Therapy, Boston)*

Eleven of 17 infusion nurse participants said they read medical device labeling while 4 of 17 infusion nurse participants said they do not read labeling. Two infusion nurse participants only partially read labeling or read labeling for some devices but not others.

Wound Care Participants

The nurse and prescriber participants specializing in wound care and who work in different settings such as hospital and home care use negative pressure wound care devices and catheters or bladder scanners. Focus group participants in different segments mentioned that they use the following other devices:

- **Prescribers:** Blood pressure cuff, hyperbaric chambers, and thermal energy devices.

- **Nurse wound care specialists:** Compression pumps, dressings/wound coverings, feeding tubes, and IV devices.

The prescribers and nurses responded differently to the question of whether they read medical device labeling.

- Among the wound care prescriber participants, three of nine do not read medical device labeling, four of nine have read labels, but perhaps not for a while, one participant has only read labeling for some devices, and one participant did not indicate whether he or she has read labeling.

- All 16 nurse wound care specialists have read medical device labeling. However, most mentioned they read labeling only in certain circumstances such as when a device is new, if they are having an issue with a device, or if they need specific information such as contraindications or allergy information (e.g., device contains latex). A participant working in a home care setting mentioned that she refers to labeling before teaching her patients to use a device.

Comparison by Segment

When considering participants in all specialties, the nurse (all specialties), nurse wound care specialist, and respiratory therapist participants appear to read medical device labeling more frequently than the prescriber participants. One possible reason that they read labeling more frequently is that more of these participants were responsible for training or providing information to their colleagues. For example, one nurse mentioned, "Yes, I always read the stuff because I had to educate the other nurses who may not read."(Nurse, Infusion therapy, New York City)

Terms Used for "Medical Device Labeling"

After the warmup, participants were asked to describe what they think of when they hear the term "medical device labeling." Among participants in all specialties and segments, other names used for medical device labeling included sticker, manual, package insert, and packaging or box. All specialties and segments think about warnings/cautions or safety information when they hear the term "medical device labeling."

Subtle themes emerged among focus group participants of different specialties regarding how they define or what comes to mind when they hear the term "medical device labeling." The respiratory therapists and respiratory nurses said they think about the device description—for example, what the device can do and what parts it has—whereas respiratory prescribers and nurses mentioned they think about instructions for use.

Infusion participants in all segments or job roles said they think about the device serial number or lot number, the company or manufacturer's contact information, and indications. A common theme discussed in both infusion nurse focus groups was that they mentioned they think of "troubleshooting" and power supply/battery information.

Wound care participants generally said they think of instructions for use, indications, and expiration dates. Nurse wound care specialists also think about contraindications, the devices' name and company contact information for the patient and health professional, and information on whether the device has been tested.

Among participants of all specialties, prescribers and nurses were similar in that both groups said they think about indications when they think about medical device labeling. However, compared to prescribers, more nurses said they think about the manufacturer's name and contact information. In addition, nurses in all specialties mentioned more details than the prescriber participants when asked what they think of when they hear the term "medical device labeling." For example, details mentioned by nurses but not prescribers included compatibility information, codes/alarms, rate/volume information, device electricity requirements, and education for patients and clinicians.

Use of Medical Device Labeling

Participants were asked to describe how they and their colleagues use medical device labeling. Additionally, they were asked to describe factors that influence the likelihood they would use labeling or, conversely, barriers to label use. Participants in all groups receive information on new medical devices from their sales representatives via an in-service. Most participants mentioned that they may refer to a manual or package insert when a device is new or for troubleshooting purposes. Overall, a health practitioner's job role seems to be the largest influence on how he or she uses the labeling and, as discussed earlier, whether he or she reads it.

Prescribers

The prescriber participants primarily rely on the in-service, manufacturer's sales representative, or support staff for information on medical devices. Many prescribers said that they skim, throw away, or delegate reading of manuals or package inserts to their staff members.

> *You sort of try to scan through it to find what you actually really need to know and … how to turn it on and how to clean it. (Prescriber, Respiratory Therapy, Philadelphia)*

> *There is something inside that you usually throw away [referring to the package insert]. (Prescriber, Infusion Therapy, Boston)*

> *I may not necessarily be the person who reads it [package insert]. Like if I have the nurses working with me and we're doing a project, I may say to her, "Here, read through this." (Prescriber, Respiratory Therapy, Philadelphia)*

In addition to referring to the manual or package insert for troubleshooting, prescribers read medical device labeling if they are on a committee responsible for purchasing medical devices. For devices they actually use on patients (e.g., usually single-use devices) as opposed to just prescribing, they might read information on the device's packaging.

> *The only other time I look at it is [if] I'm on one of the hospital committees where we have to decide if it's something that we're going to be using or not and then I absolutely look at it and that's probably the only time I consistently look at something. (Practitioner, Wound Care, New York City)*

Nurses/Nurse Wound Care Specialists

Nurse and nurse wound care specialist participants spend more time reading device manuals than prescriber participants. The infusion and respiratory nurses said that they use the manual to learn more after they have received an in-service.

> *They do give you a little bit of an in-service, but you do look through the manual just to get a little more information and you keep it there in case you need to refer back to it. (Nurse, Respiratory Therapy, Boston)*

> *We usually do [read it], especially if we have a problem after [the manufacturer's representative] left. (Nurse, Infusion Therapy, New York City)*

The nurses who are responsible for training others to use medical devices often meet with the sales representative then take the manual home to read before an in-service. In fact, nurses in managerial roles sometimes lead the in-service instead of the device manufacturer's sales representative.

> *All of us are in a managerial role so we do have to take that manual, that book home and then, you know, kind of read it and study it, and then have it presented to your staff. (Nurse, Infusion therapy, Philadelphia)*

Instead of using a manual or booklet, some of the wound care specialist participants mentioned that they often listen to instructions on the device itself or on a CD. When they are learning to use a new device, they often learn collaboratively as someone acts as a "guinea pig" so they can practice using the device before using it on a patient.

> *So, you know, you sit there and you… listen or read it. Then you find somebody in the office to use as a guinea pig to practice on them, and that's it. (Nurse Wound Care Specialist, Philadelphia)*

Respiratory Therapists

Like nurses, respiratory therapists said they read the manual at their leisure to learn information not covered or missed during an in-service. Often they file the labeling or attach it to the machine after the in-service because they are responsible for disseminating the device labeling information to doctors and nurses.

> *I immediately take it up and put it in a folder, you know, to store because after what everybody said, after the in-services and continuing education, there's still questions because you have to disseminate that to the doctors, nurses, and the other disciplinarians that's throughout the hospital. (Respiratory Therapist, New York City)*

Influences/Barriers to Label Use

Overall, participants in all segments gave similar responses when asked about influences and barriers to label use. Participants said they were more likely to read device labeling in the following circumstances:

- When they are troubleshooting.
- If they are unfamiliar with a device.
- To prevent a life-threatening circumstance for a patient.
  - Participants are more likely to read labeling for devices that if operated improperly could cause life-threatening circumstances for patients; likewise they are more likely to read the warning information on the label.
  - If the patient has an allergy to a material such as latex, the practitioner is more likely to read the labeling to prevent a potentially life-threatening reaction.
- If the labeling is "quick" and easy to read.
- If the label is "handy" or easily accessible.

The nurse, nurse wound care specialist, and respiratory therapist participants also mentioned that they are more likely to read labeling if they are responsible for training or helping others to use a device. For example, one respiratory therapist said:

> *You're the information guru supposedly, you know, so you sort of have to stay on top of the game. (Respiratory Therapist, New York City)*

Because participants mentioned that they do not have much time to spend reading medical device labeling, barriers to using it included if the length of the document is too long, if the language is difficult to understand (e.g., too wordy, technical, or in "legalese"), or if the formatting is difficult to read such as if the font size is too small. Prescribers also mentioned a barrier to reading labeling is if it easily rips or tears.

> *If the language is too… highly technical, you know, you have to be an astronaut to understand, people aren't going to look at that. (Nurse Wound Care Specialist, New York City)*

> *The words are all in the same font and not bolded unless it says, 'Indications' so it's just like a run-on sort of sentence. (Prescriber, Infusion Therapy, Boston)*

> *You need a magnifying glass to read it. (Prescriber, Wound Care, Boston)*

> *It's on like tissue paper-like paper so it easily rips or tears. (Prescriber, Wound Care, Boston)*

Access to Medical Device Labeling

Most doctor's offices or hospitals have a designated location for device manuals. This location can be a file folder or binder at a nurse's station or other designated storage area. However, participants working in home settings said they do not have a designated area for manuals. Although many participants said their practices have an area for manuals, they are not always easily accessible. They might be difficult to find in the bottom of a drawer or they are locked away in a storage room or office.

We have like 10 rooms, and so there's a central nurse's station there, all the manuals are there. (Prescriber, Infusion Therapy, Philadelphia)

Yeah, we're required to keep bulk kind of manuals for inspection purposes available probably, you know, so they are somewhere but they're… in a storage room on your unit somewhere. (Nurse, Respiratory Therapy, Boston)

Except for prescribers specializing in infusion therapy, participants said they primarily look online for labeling information by searching for the medical device's name or product number.

You Google any one of these products and you can pretty much pull up any of the product information on them. (Prescriber, Wound Care, New York City)

Just Google it, whatever you're looking for. (Respiratory Therapist, New York City)

No, sometimes, you know, it's easier to go online and look for it rather than to look around the office. (Prescriber, Infusion Therapy, Philadelphia)

Many participants in all segments and specialties also mentioned that they look for device labeling directly on the device itself. Sometimes nurses attach labeling to the device, so they will have easy and convenient access to this information at the "point of care."

I remember one pump that the manual was actually attached to it. (Nurse, Infusion Therapy, New York City)

I notice sometimes the nurses will print out something and like of the troubleshooting one, you've also even seen it probably laminated on a little ring and attached to the back of the machine. (Prescriber, Infusion Therapy, Boston)

Yeah, if it's clipped to the machine you're fine, you're golden, but otherwise it's kind of random. (Nurse, Respiratory Therapy, Boston)

In addition to looking for labeling information directly on a device, the wound care participants often refer to the devices' packaging or a package insert for labeling information.

[Labeling is] usually …on the device itself or packaged with the device. (Prescriber, Wound Care, New York City)

Yeah, you can look at the box and if there's nothing on the box then you look in the box. (Nurse Wound Care Specialist, Philadelphia)

The prescribers, nurses, and nurse wound care specialists mentioned they will often call the manufacturer (e.g., phone number on the machine) or manufacturer's representative for labeling information, in particular if they are having difficulty finding it.

You could go online or there'll be a phone number on the machine you have to call. (Nurse, Respiratory Therapy, Boston)

You can always call the company. (Nurse, Respiratory Therapy, Philadelphia)

Among the specialty groups, the respiratory and wound care participants said at times they have difficulty finding the medical device labeling for certain devices, whereas the infusion therapy participants generally did not seem to have difficulty accessing medical device labeling.

> *There are times I can't find [labeling]. For example, the beds, like pressure-reduction mattresses, I can't find those things. (Prescriber, Wound Care, New York City)*

> *Some of these things that you're looking for you can't always find or you don't even know where to look. (Nurse, Respiratory Therapy, Boston)*

Content of Labeling

Participants were asked to list sections of medical device labeling they find most important to them. Following this, participants were asked to identify sections of medical device labeling they find least important or least useful and whether there is information missing in medical device labeling that would be important or useful to them. We asked participants to review a list of 13 topic areas of medical device labeling (Appendix G) and asked them to rank order these sections in order of importance for medical device labeling.

Participants were shown sample medical device labeling specific to their specialty (infusion, respiratory, wound care) with identifying information redacted, for use while discussing the topic areas for labeling. Participants were specifically instructed not to focus on the specific medical device but rather comment on the content and format by considering this as an example of labeling.

Important Sections of Medical Device Labeling

As noted above, some participants in the prescriber groups and nurse groups reported reading device labels in their entirety, especially for new products, to become familiar with the product and therefore felt that all sections on medical device labeling were of equal importance. In six of the nine groups, at least one participant noted that all sections in medical device labeling are important for legal reasons:

> *Sometimes you just look and say, "Oh, that's there for some legal reason. Somebody did something and now it's labeled." Legalese. (Nurse, Infusion Therapy, Philadelphia)*

> *Open the package, take out the insert and actually review it and read it and make sure all the products are within the package that you're looking for and then go in and do what you need to do with the patient. [I read it thoroughly in its entirety] Especially if I was unfamiliar with the product. (Nurse Wound Care Specialist, Wound Care, Boston)*

> *As far as medical labels go, I've been doing this for years so you will not see me reading a label if I've used the product over and over again, but if it's a new device or if it's a new application, then certainly that's something that I would review. (Nurse Wound Care Specialist, Wound Care, Boston)*

> *You have to read it when it comes, to become familiar with the product. (Nurse, Infusion Therapy, Philadelphia)*

If it's really long I might take it home and read it, yes, but if it's something maybe ten to twelve pages or less, I will actually skim through it and get a gist because it may be some setup things that you need to do for that particular product. (Nurse, Infusion Therapy, Philadelphia)

Since prescribers do not read or use labeling as frequently as nurses and respiratory therapists (as presented previously in this report), participants in the prescribing groups had less input on important sections of medical device labeling. Overall, prescribers identified fewer sections of the medical device labeling as important/useful to them compared to nurses and respiratory therapists.

Participants in all nine groups identified the following as *important and useful* sections of medical device labeling:

- troubleshooting
- instructions for use
- warnings
- precautions
- adverse events and contraindications
- device name
- information on parts/contents of the medical device package
- serial number and expiration date
- manufacturer's contact information including a toll-free phone number (available for troubleshooting 24 hours a day) and a website

Particpants were then asked which of the 13 topic areas were most important and useful. All participants across nine focus groups, three specialties and three geographic locations agreed that the *most important and useful* sections of medical device labeling were the following:

- instructions for use
- troubleshooting
- warnings
- precautions
- contraindications
- adverse events
- manufacturer's contact information

- lot number/serial number

Quotes from participants about the importance of certain sections included:

> *I'll skim and look for warnings, that kind of thing. And if there's a problem you always read it. Using it, using it, yeah, troubleshooting. (Prescriber, Wound Care, New York).*

> *Contraindications and Warnings and Precautions…they're all, that's really the same. (Nurse Wound Care Specialist, Wound Care, Boston)*

> *I've been doing this for 26 years so, you know, some packaging has changed over time. There are many things that I don't read the labels any longer, but certainly the first time … because I want to make sure there are no… contraindications, indications, allergies, things such as that.. (Nurse Wound Care Specialist, Wound Care, Boston)*

> *I think Warnings and Precautions should be first, what not to do first. (Respiratory Therapist, Respiratory Therapy, New York)*

> *Yeah, you look at the label and call, even call the company to make sure they're…compatible. So the product in and of itself may not be a problem but in combination with something else it could be. (Prescriber, Wound Care, New York)*

> *Tech support number. It's very important. I used to call many times. (Respiratory Therapist, Respiratory Therapy, New York)*

Additionally, several participants in each group across all locations also identified that pictures, graphics, and diagrams describing the device parts, instructions for use, and troubleshooting are useful and important.

> *I think diagrams of devices are important to make it easier. (Prescriber, Infusion Therapy, Boston)*

> *Also, too, you would like to have diagrams to match the words to make sure people are actually picturing in their mind because some of us are visual [learners]. (Nurse, Infusion Therapy, Philadelphia)*

> *Pictures are good because if you just look at them and you can look at them while you're doing stuff and it helps. (Prescriber, Wound Care, New York)*

A couple of participants in each group highlighted the importance of indications, use in special populations (e.g., children, age group, weight group), cleaning and maintenance, power supply and compatibility information, list of frequently asked questions, and table of contents as additional information on medical device labeling as useful/important.

However, there was no consensus on the importance of these sections among prescribers, respiratory therapists, and nurses. Prescribers saw indications and use in special populations as aspects of device labeling a physician should know by the time he or she uses a device and hence not important to refer to. Most nurses across all specialties noted these sections as important. However, a couple of participants, including nurse participants, also felt that these were less important than instructions for use,

warnings and troubleshooting and could therefore be excluded from the shorter version of the medical device label. Thus, overall, these sections of medical device labeling were clearly identified as of *medium* importance by participants in this study, irrespective of their specialty, role, and geographic location.

> *As I said before, I think indications, if you don't know the indication you shouldn't be using the device. (Prescriber, Respiratory Therapy, Philadelphia)*
>
> *That's for attorneys to read to find out that you didn't use it for an FDA-approved indication so they can sue you. It's really not for the practitioner to use. (Prescriber, Respiratory Therapy, Philadelphia)*
>
> *But if you were going to buy the device as a practitioner wouldn't you want to know what it was used for? (Prescriber, Respiratory Therapy, Philadelphia)*
>
> *I think you'd want to know before you're even looking at it, before you go into the market for it, I think you'd know [indications]. (Prescriber, Respiratory Therapy, Philadelphia)*
>
> *Indications might be at the top because sometimes you might get the wrong device but you think it might be the right situation or a piece of equipment and you realize, "I got the wrong equipment." (Nurse, Infusion Therapy, New York)*
>
> *Use in specific populations, that's a very good point, like if it's something that's not to be used for children. (Nurse Wound Care Specialist, Wound Care, Boston).*

Several prescribers in wound care, infusion therapy, and respiratory therapy prescriber groups noted that they are not responsible for the cleaning, reuse, disposal, and maintenance of devices and that they rely on ancillary support (device technicians, nurses, biomedical technicians) for cleaning and maintenance. This made cleaning and maintenance sections of device labeling less useful/relevant to them.

> *One thing I access is the machine. I mean, if it's a dialysis machine you're probably going to call the nurse and probably a technician to come up. You have no idea what, I mean, don't break the machine. You don't want to get into that…Ancillary help…You're calling ancillary help. (Prescriber, Infusion Therapy, Boston)*

Participants across all nine focus groups gave suggestions for additional information for inclusion in a comprehensive medical device label, although not information they would need as often:

- Respiratory and infusion nurses recommended information on how to correct mistakes or "worst case scenarios."
- Practitioners mentioned troubleshooting.
- Wound care and infusion nurses indicated the need for information on cleaning/maintenance and disposal of disposables.
- Wound care nurses and practitioners recommended inclusion of expiration dates—they can be difficult to find.

- Respiratory therapists mentioned the need for a better table of contents or index.

Least Important Sections of the Device Labeling

Focus group participants across all specialties and geographic locations noted several sections of medical device labeling as least important. All groups noted that clinical studies and references were least important. "Clinical studies, which would be part of the references…would probably be the last thing we'd look at." (Prescriber, Respiratory Therapy, Philadelphia)

However, In five of the nine groups, at least one participant in each group noted the importance of retaining these sections because they form the evidence base for medical devices.

> *No, I think it [references and clinical studies] would be important if somebody came to you, was having a problem with a device and… I would look at the references to see how the equipment had been used in the past, and I would like the see the clinical trials. (Prescriber, Respiratory Therapy, Philadelphia)*

> *I might want to see how well the device works and how many people they've done studies with it or are they just marketing it as such a device to be effective. (Prescriber, Respiratory Therapy, Philadelphia)*

> *I might want clinical studies. Because it's… evidence-based. It can tell you where it went good and where it went bad. (Respiratory Therapist, New York)*

Rank Ordering

The findings from the rank ordering exercise mirrored input provided by participants in each of the nine groups in response to questions about identifying important and less important sections of medical device labeling during the early part of each focus group discussion. They also mirrored and represented previously discussed variations in perspectives among prescribers and nurses. All focus groups were consistent in their feedback and ranked the following sections as most important:

- warnings/precautions
- contraindications
- adverse events
- instructions for use
- device description
- manufacturer-contact information

Additionally, a couple of participants in each group noted they liked the format of the list of 13 for an index/table of contents for medical device labeling.

All focus groups ranked clinical studies and references lowest during the rank ordering exercise, but recommended retaining these sections, perhaps in a longer label version.

> *I'm with you about the clinical studies and references, it's something that needs to be there pushed way in the back. I'm not saying it shouldn't be there. (Prescriber, Respiratory Therapy, Philadelphia)*

The section "how supplied" was not discussed and ranked by any participant in seven of the nine focus groups; in one focus group, participants were unclear what it means and in another, participants ranked this section among the least important.

Participants were also uniform in their assessment of the importance of indications and usage, use in specific populations, health professional training, and patient counseling and training during the rank ordering exercise. They ranked these as of medium importance during the rank ordering exercise. All focus groups ranked health professional training, use in specific populations, and patient counseling and training above clinical studies and references. Nurses across all three specialties and all three geographic locations were more likely than physicians/nurse practitioners (prescribers) to rank these as important.

There were clear differences between prescribers and nurses on retaining these sections of medium importance in medical device labeling. Although several participants in prescriber groups and a couple in the nurses group noted these of less importance and identified these as potential sections for exclusion from the device label, the vast majority of participants in the nurses groups indicated the importance of retaining these sections in device labels.

> *I would say take out Professional Training because I think that's going to be institution specific. You know, if somebody does hyperbaric, then that's going to be, they're going to have their own manuals and procedures….The whole purpose of this is for health professional training, this book. That's what this book is for. (Nurse Wound Care Specialist, Wound Care, Boston)*

> *Because we precept a lot of wound and ostomy students so labeling and packaging inserts are very important to us in that regard…So we actually pick up the instructions of use, we open it up, there is instructions written as well as pictures and we will go step by step, somebody will read them and somebody, the student will actually do the application of the dressing. We make it a point to read everything from the labels when you're doing your teaching, and we all teach… students. (Nurse Wound Care Specialist, Wound Care, Boston)*

Prescribers and nurses across all three specialty and all three geographic locations who were involved in a training/teaching role within their employment setting were similar in their ranking of importance of health professional training because they were reflecting on the importance of this section as relevant and important from their perspective as a trainer/teacher in the health care system.

Prescribers and nurses who were involved in teaching patients how to use medical devices reported that patient counseling and user training were important sections, primarily reflecting their role as patient educators and thus, the difference between their role as prescribers versus nurses did not play a role in their assessment of the importance of this section of medical device labeling.

Suggested Changes to Content and Format of Labeling

Participants were asked how they would change medical device labeling to make it more useful or increase its use by healthcare practitioners. Across all groups, irrespective of specialty, geographic location, or practitioner type, participants recommended changes to the length, font size, format of delivery, mode of access, content, and amount of information, and recommended inclusion of specific elements to make it user friendly.

All groups would like a shorter version of labeling to improve and increase use. Many participants referred to this shorter version as a "quick reference guide," "cheat sheet," or "pocket guide." Participants want something they can use *quickly* while they are working with patients, perhaps at their bedside.

> *"The barrier of reading the short guide was nothing. The barrier to reading the long guide was that it was a longer guide." (Philadelphia, Practitioners, Respiratory Therapy)*

> *Something small and quick and easy, you know, that you have at the bedside that you can look at like a quick and easy sheet. (Nurse Wound Care Specialist, Wound Care, Boston)*

> *There is so much text and sometimes you just want a summary of it to evaluate it from the get go. (Prescriber, Wound Care, New York)*

> *Because most of the time you're a little bit too busy…to read through a lengthy manual, so it has to be something short, sweet, and to the point. (Nurse, Wound Care, Philadelphia)*

> *Maybe… you should have a short list and a long list … one that just goes strictly to the meat and then something in-depth later… pocket-size… you can carry it with you. (Respiratory Therapist, New York)*

Several participants noted the need for simple instructions with a picture and diagrams and strongly indicated preference for shorter length and larger font, use of color/bold letters to distinguish headings, lamination of hardcopy medical device labeling, and creating a highlights section (shorter version) with elements identified as most important and excluding elements identified as least important.

> *I think if it's… overly wordy, overly technical when it doesn't need to be—basically you want something that's really functional, user-friendly, and it, and it's going … bring you up to speed right away. Something technical might be fine for a technician. (Nurse, Infusion Therapy, Philadelphia)*

> *It needs to be concise and … the content needs to be laid out appropriately and obviously safety being, I would say, probably at the front…especially for administrators and managers. (Nurse, Infusion Therapy, Philadelphia)*

> *I was going to say if they could make maybe quick reference cards, something that would be small like a quick, you know cheat sheet or for lack of a better word on how to, you know, do a quick startup just as a friendly reminder kind of quick thing. (Philadelphia, Nurse, Infusion Therapy)*

I would say simple, picture, diagrams, sometimes bigger wording. (Nurse, Infusion Therapy, Philadelphia)

Very simple instructions, like one or two sentences with a picture, number it, not too lengthy. Because most of the time you're a little bit too busy to read through a lengthy manual, so it has to be something short, sweet, and to the point. (Nurse, Wound Care, Philadelphia)

…but I think diagrams and algorithms and pictures, again, make me want to look at something because you can look at a picture and a diagram and then if you need more information you can go over and read the text. (Nurse, Wound Care, Philadelphia)

…something that can … remind you of what you were told in the in-service or … the basic information. (Nurse, Wound Care, Philadelphia)

Keep it simple. (Nurse, Wound Care, Philadelphia)

Well [on the shorter version], first of all [include] your troubleshooting, your help number, setting it up, operation, indications, contraindications, you know, just basic stuff just to get started and if you get in trouble where to go from there because sometimes when you're upstairs on the floors or you're in the, in the unit, you can't run all the way back down to the office and so on. You have it in your pocket or something, you can put it on the unit or have access to it. (Respiratory Therapist, New York)

Colors, colors always, you know, get my attention. (Respiratory Therapist, New York)

Presentation of Labeling

Participants were asked in what format they would like to see labeling presented. The majority of groups (n=6) said they wanted the labeling attached to the actual device, or at least the important details needed to be attached. Ideas for attaching the information included a laminated and easily disinfected card attached to the device, a metal plate affixed to the device, or having the information available on the LCD display for display-equipped devices. When attaching the label, one group said the label should be permanently affixed rather than using paper:

One of the issues with attaching the label to the machine is that when the machine undergoes cleaning there is a lot of times you have to take it off, and then there are some instruction control issues, what do you do with the potential for the infectious breakout between the label and the machine? How do you clean that? There is a possibility of, you know, bacterial contamination so… I like when the labels are permanently affixed, whether it's aluminum or engraved kind of a label rather than a paper label because a paper label can come off and even when you put plastic on a lot of the times, it peels off over a period of time. (Respiratory Therapist, New York City)

Two groups reiterated that they would want to hear key information from the equipment manufacturer representative during in-service visits.

There are a lot of tips that they then give you that are not going to be written in the manual, things they've discovered by visiting other institutions or places that have used

the device more, and experience is very important in how one uses a device. (Practitioner, Respiratory Therapy, Philadelphia)

One group suggested putting label information on the box that the equipment is packed in; however, another group said not to use the box as a place to put information.

The box is gone. [Laughter] I mean, you may not ever see the box. In an office-based practice you might but in a hospital-based practice—[no]. (Practitioner, Respiratory Therapy, Philadelphia)

We probed participants further to elicit their opinions on ways they would like the labeling made available to them (for instance online, PDA, trainings, written). Three groups agreed that they would want the labels made available online whereas one group (nurse wound care specialists) did not.

You might not be able to get to a computer you know, at that moment. Later might be great but you might not be able to do it right then.(Nurse Wound Care Specialist, Philadelphia)

Groups were split about whether the label should be available on a PDA or cell phone with three groups (nurse infusion specialist, respiratory therapists, and nurses speciliazing in respiratory therapy) supporting and two (wound care practicioners and nurse wound care specialists) against it. A reason given for not wanting the label as a cell phone application (e.g., iPhone, Android, or Blackberry) was because of a lack of cell phone coverage and data signal in hospitals. "We absolutely would not. People can't even get their phone calls in our office, so absolutely not" (Practitioner, Wound Care, New York City) was a representative dissenting view. "Well, a lot of people that have the Smart Phones can go online, too, with their Smart Phone so to have the app would be even faster." (Nurse, Infusion Therapy, Philadelphia) was one supporting opinion.

Participants were asked if they would like an online repository of labels and if they thought FDA's website would be a good place to house labels available electronically. The majority of groups (n=5) said that having the information on the FDA's website was a good idea, two groups (respiratory practioners and nurses specializing in infusion therapy) did not support the idea and the nurse wound care specialist group was mixed on their opinions. Participants said a main concern of housing the information on FDA.gov is having it organized.

It's just, it's like the government. It's like trying to find something—it's like, Where do I, how many layers do I have to peel back to find this one answer?… [It's] like the last scene of Indiana Jones where you see that big warehouse. It's like, "Oh, my God." (Nurse, Infusion Therapy, Philadelphia)

A participant in a group that was in favor of a repository of labeling on the FDA website stated, "Yeah, because I know that that information is supposed to be objective. Sometimes you go to the company website, you get their slant on stuff, like the sales pitch." (Nurse Wound Care Specialist, Philadelphia) In one group, the participants said they would implicitly trust information that was placed on FDA's website. "You know, if the FDA puts their seal on things you tend to take it at face value. It's like the *Good Housekeeping* seal if it's FDA approved." (Nurse, Respiratory Therapy, Boston)

Awareness of Changes in Labeling Content

There is currently no standardized way that practitioners receive information on changes in labeling content. Some practitioners stated that they hear about changes from the device representatives, others report receiving an e-mail or hearing from a coworker, but most reported that they only know something is "wrong" with the device when it stops working correctly or a new device replaces it. Infrequently, practitioners get information about recalls (not changes in labeling specifically) from their hospital education or quality improvement/risk management department. Although some practitioners reported receiving letters mailed when a device is recalled, they also reported that they often throw these letters away, unopened.

Practitioners were asked if they had ever received information about medical device labeling changes from their professional societies. None of the participants reported hearing about device labeling changes from these sources.

When asked how they would like to hear about changes to device labels, practitioners had differing opinions depending on their role. Prescribers recommended that they be informed by the person in their setting whose role it is to coordinate changes to devices.

> *E-mail the person at the hospital whose job it is to keep up with this stuff and have them point it out to me. (Wound Care Prescriber, New York City)*

Many of the nurses, therapists, and other allied health professional participants would like to be subscribed to an e-mail service from the manufacturer that would inform them of changes to the labeling, recalls, or new black box warnings. Some suggested that the information be "triaged" based on urgency. One group of nurses (infusion therapy, Philadelphia) reported that they are expected to check the hospital intranet each month for information about recalls; they would expect to hear about labeling changes on the intranet as well.

Recommendations

Key findings from the focus groups have led to the following recommendations:

Labeling Sections

- Consider creating a shorter device label with the sections seen as most important in addition to keeping the current detailed, longer manual. The sections that were identified as most important were:
  - instructions for use
  - troubleshooting
  - warnings
  - precautions
  - contraindications
  - adverse events
  - manufacturer's contact information
  - lot number/serial number
- The labeling sections identified as least important should be retained in the longer version of the medical device labeling because some participants reported these as useful, especially if contained within a longer label.
- The sections in medical device labeling identified as least important—clinical studies and references—would benefit from a careful review in light of FDA and regulatory requirements and scientific evidence on the importance of these sections from other stakeholders.
- The importance of all sections should be carefully reviewed in light of FDA and regulatory requirements given that some participants were concerned about liability issues.

Labeling Format

- Because the primary users of medical device labeling are nurses and therapists, medical device labeling should be designed and written with consideration of the needs of these audiences.
- Medical device labeling should be short, concise, and easy to comprehend quickly.
- Consider including only content that will enhance practitioners' understanding of how to properly operate a device or how this device might enhance the quality of a patient's care and minimize risks.
- Consider changing the content and format of medical device labeling, including larger font size, color; concise, simple, and user-friendly medical device labeling; less information, and less technical language; more pictures and diagrams to match instructions of use and device contents; and troubleshooting text.

Access to Labeling

- A shorter version of medical device labeling should be provided in such a manner that it can be accessed quickly and easily while practitioners are working with patients. RTI suggests possible methods for disseminating medical device labeling include online or directly on the medical device. One way to combine these methods is to put a Quick Response (QR) code on the device. When this QR code is scanned with a camera phone or phone with a barcode reader it will instantly take you to a webpage with the device's labeling information.

- Consider supplementing hardcopy labeling with electronic versions.

- Consider working with device manufacturers and their sales representatives to disseminate labeling information, because practitioners have become accustomed to relying on these groups for information.

- Consider working with device manufacturers to disseminate changes to device labeling by e-mail with a uniform format. These e-mails should go to identified contacts in each setting, with the contacts being identified by manufacturer representatives.

- Important information from medical device labels should be affixed to the device, either by a metal plate, imprinted on the device, or a laminated card attached to the device. Using the shipping box to place important information is less effective.

- Consider collecting all medical device labels in an accessible database on FDA's website. However, to be effective, the database and website would need to be easy to navigate and logically organized. Practitioners should be able to search by any or all of the following:

    - The name of the device

    - The model number

    - The serial number

    - The name of the manufacturer

- Consider future research to determine patient and caregiver search terms that would enable effective searching in a labeling database.